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AMENDMENT UNDER 37 CFR 1.111  
Examining Group 1651  
Patent Application  
Docket No. SPO-121

September 16, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner : Satyendra K. Singh  
Art Unit : 1651  
Applicants : Hisae Kume *et al.*  
Serial No. : 10/535,585  
Conf. No. : 7558  
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For : Nutritional Compositions

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
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SUPPLEMENTAL AMENDMENT UNDER 37 CFR 1.111

Sir:

In response to the Office Action dated June 5, 2007, please amend the above-referenced patent application as follows:

**Amendments to the Claims** are reflected in the listing of claims beginning on page 2 of this paper.

**Remarks/Arguments** follow the amendment sections of this paper.

In the Claims:

This listing of claims will replace all prior versions and listings of claims in this application.

1 (Currently amended). A nutritional composition for liver disease patients comprising: a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate, ~~wherein the protein content is 2.9 to 9 g per 100 mL of the composition.~~

2 (Previously presented). The nutritional composition according to claim 1, wherein the source of said milk protein hydrolysate is selected from the group consisting of casein, a milk protein concentrate (MPC), a whey protein concentrate (WPC), a whey protein isolate (WPI),  $\alpha$ -lactoalbumin,  $\beta$ -lactoglobulin, and lactoferrin.

3 (Original). The nutritional composition according to claim 1, wherein said fermented milk-derived protein is from a composition in which the whey in fermented milk has been reduced.

4 (Original). The nutritional composition according to claim 1, wherein said fermented milk-derived protein is from fresh cheese.

5 (Original). The nutritional composition according to claim 4, wherein said fresh cheese is quark.

6 (Previously presented). The nutritional composition according to claim 1, wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with endoprotease from *Bacillus licheniformis*, and trypsin from a porcine pancreas.

7 (Previously presented). The nutritional composition according to claim 6, wherein the milk protein hydrolysate is a permeate obtained by further treatment with an ultrafiltration membrane having a fractionation molecular weight of 10,000 Da.

8 (Previously presented). The nutritional composition according to claim 7, wherein the chromatogram from reverse phase HPLC separation of the milk protein hydrolysate is shown in Fig. 1.

9 (Previously presented). A nutritional composition for patients under high levels of invasive stress, wherein said nutritional composition comprises: a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.

10 (Previously presented). The nutritional composition according to claim 9, wherein the source of said milk protein hydrolysate is selected from the group consisting of casein, a milk protein concentrate (MPC), a whey protein concentrate (WPC), a whey protein isolate (WPI),  $\alpha$ -lactoalbumin,  $\beta$ -lactoglobulin, and lactoferrin.

11 (Original). The nutritional composition according to claim 9, wherein said fermented milk-derived protein is from a composition in which the whey in the fermented milk has been reduced.

12 (Original). The nutritional composition according to claim 9, wherein said fermented milk-derived protein is from fresh cheese.

13 (Original). The nutritional composition according to claim 12, wherein said fresh cheese is quark.

14 (Previously presented). The nutritional composition according to claim 9, wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with endoprotease derived from *Bacillus licheniformis*, and trypsin from a porcine pancreas.

15 (Previously presented). The nutritional composition according to claim 14, wherein the milk protein hydrolysate is a permeate obtained by further treatment with an ultrafiltration membrane having a fractionation molecular weight of 10,000 Da.

16 (Previously presented). The nutritional composition according to claim 15, wherein the chromatogram from reverse phase HPLC separation of the milk protein hydrolysate is shown in Fig. 1.

17 (Previously presented). A method for providing nutrition to a patient having liver disease and/or a high level of invasive stress, wherein said method comprises administering, to such a patient, a nutritional composition that comprises:

a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.

18 (Previously presented). The method according to claim 17, wherein the source of said milk protein hydrolysate is selected from the group consisting of casein, a milk protein concentrate (MPC), a whey protein concentrate (WPC), a whey protein isolate (WPI),  $\alpha$ -lactalbumin,  $\beta$ -lactoglobulin, and lactoferrin.

19 (Previously presented). The method according to claim 17, wherein said fermented milk-derived protein is from a composition in which the whey in fermented milk has been reduced.

20 (Previously presented). The method according to claim 17, wherein said fermented milk-derived protein is from fresh cheese.

21 (Previously presented). The method according to claim 20, wherein said fresh cheese is quark.

22 (Previously presented). The method according to claim 17, wherein said milk protein hydrolysate may be obtained by hydrolyzing a whey protein isolate (WPI) with endoprotease from *Bacillus licheniformis*, and trypsin from a porcine pancreas.

23 (Previously presented). The method according to claim 22, wherein the milk protein hydrolysate is a permeate obtained by further treatment with an ultrafiltration membrane having a fractionation molecular weight of 10,000 Da.

24 (Previously presented). The method according to claim 23, wherein the chromatogram from reverse phase HPLC separation of the milk protein hydrolysate is shown in Fig. 1.

25 (Previously presented). A method for suppressing hepatitis in a patient in need thereof, wherein said method comprises orally administering to such a patient, a nutritional composition that comprises:

a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.

26 (Previously presented). A method for improving the pathological condition of inflammatory disease patients, wherein said method comprises orally administering to such a patient, nutritional composition that comprises:

a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.

27 (Previously presented). A method for suppressing inflammatory cytokine production in a patient in need thereof, wherein said method comprises orally administering to such a patient, a milk protein hydrolysate.

28 (Previously presented). A method for suppressing hepatopathy in a patient in need thereof, wherein said method comprises orally administering to such a patient, a milk protein hydrolysate.

29 (Previously presented). A method for providing nutrition to a patient with liver cirrhosis, wherein said method comprises administering to such a patient, a nutritional composition that comprises:

a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and palatinose as a carbohydrate.

30 (Previously presented). A method for providing nutrition to a patient with hepatic failure, wherein said method comprises administering to such a patient, a nutritional composition that comprises:

a milk protein hydrolysate in an amount of 0.9 to 3 g per 100 mL of the composition and a

protein derived from fermented milk in an amount of 2.5 to 4.5 g per 100 mL of the composition as proteins; a high oleic acid-containing oil and milk lecithin and/or soybean lecithin as lipids; and a palatinose as a carbohydrate.

Remarks

This Supplemental Amendment is being submitted further in response to the Office Action dated June 5, 2007 to correct an error made in amending claim 1 as well as a typographical error in the remarks section.

By this Amendment, the applicants have further amended claim 1 as stated in the remarks section of the Amendment filed on August 27, 2007. Specifically, claim 1 has been amended to specify the content of milk protein hydrolysate to be 0.9 to 3 g per 100 mL of the composition, and the content of protein derived from fermented milk is 2.5 to 4.5 g per 100 mL of the composition. As stated in the previous Amendment, support for the amendment to claim 1 can be found at, for example, page 10, lines 26-27 and page 11, lines 7-8 of the specification.

The applicants' further wish to amend the remarks section of the Amendment dated August 27, 2007 to correct a typographical error on page 9, 2<sup>nd</sup> paragraph, wherein it is stated "comprised digestive systein" should read "compromised digestive system."

No new matter has been added by this Supplemental Amendment. Claims 1-30 remain before the Examiner for consideration.



In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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